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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,943	10/16/2003	Andrew McMichael	2907.1000-003	4585

21005 7590 07/05/2006

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EXAMINER	
HUMPHREY, LOUISE WANG ZHIYING	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/686,943	MCMICHAEL ET AL.	
	Examiner	Art Unit	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *8,9,11,13,17-26,29,30,34 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10,12,14-16,27,28 and 31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/454,204.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/6/04, 10/28/04, 5/18/06*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Office acknowledges the receipt of Applicant's election and Amendment, filed on 18 May 2006.

Election/Restriction

Applicant elects the sequence of SEQ ID NO:64, and the species of a replicating viral priming vector and a non-replicating fowlpox boosting vector. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-35 are pending. Claims 8, 9, 11, 13, 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention/species.

Claims 1-7, 10, 12, 14-16, 27, 28, and 31-33 are examined to the extent that they read on the elected species.

Information Disclosure Statement

An initialed and dated copy of each of Applicant's IDS form 1449, filed on 06 July 2004, 28 October 2004, and 18 May 2006, respectively, is attached to the instant Office action.

Specification

Applicant is required to update the status (pending, allowed, etc.) of all parent priority applications in the first line of the specification. The status of all citations of US filed applications in the specification should also be updated where appropriate.

Double patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Gosteli*, 872 F.2d 1008, 1010, 10 USPQ2d 1614, 1616 (Fed. Cir. 1989); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782, 227 USPQ 773, 779 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 10, 14-16, 27, and 31-33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5-7, 15-18, and 20 of U.S. Patent No. 6,663,871. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic

to all that are recited in the patented claims, that is, the patented claims fall entirely within the scope of the instant claims or, in other words, claims 1-6, 10, 14-16, 27, and 31-33 are anticipated by claims 1, 2, 5-7, 15-18, and 20 of U.S. Patent No. 6,663,871.

The following are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Claims 1-3, 6, 7, 10, 12, 14, and 15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 9, 11, 13, and 14 of copending Application No. 10/833,439. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic to all that are recited in the patented claims, that is, the patented claims fall entirely within the scope of the instant claims or, in other words, claims 1-3, 6, 7, 10, 12, 14, and 15 are anticipated by claims 1, 4, 5, 9, 11, 13, and 14 of copending Application No. 10/833,439.

Claims 1-3, 6, 7, 10, 12, 14, and 15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 9, 11, and 13-16 of copending Application No. 10/833,744. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic to all that are recited in the patented claims, that is, the patented claims fall entirely within the scope of the instant claims or, in other words, claims 1-3, 6, 7, 10, 12, 14, and 15 are anticipated by claims 1, 4, 5, 9, 11, and 13-16 of copending Application No. 10/833,744.

Claims 1-3, 5-7, 10, 12, 14, and 15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 9, 11, and 13-15 of copending Application No. 10/833,745. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic to all that are recited in the patented claims, that is, the patented claims fall entirely within the scope of the instant claims or, in other words, claims 1-3, 5-7, 10, 12, 14, and 15 are anticipated by claims 1, 4, 5, 9, 11, and 13-15 of copending Application No. 10/833,745.

Claims 1, 6, and 27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 6-8 of copending Application No. 10/653,624. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic to all that are recited in the patented claims, that is, the patented claims fall entirely within the scope of the instant claims or, in other words, claims 1, 6, and 27 are anticipated by claims 1-5 and 6-8 of copending Application No. 10/653,624.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6, 7, 10, 12, and 14 are rejected under 35 U.S.C. §102(b) as being anticipated by Hodge *et al.* (1997, Apr-May, Ref. No. AU3 in IDS filed on 06 July 2004).

The instant claims are drawn to a method of generating CD8+ T cell immune response in a mammal against at least one target antigen, comprising administering to the mammal one priming viral vector and a boosting non-replicating viral vector expressing CD8+ T cell epitopes of the target antigen.

Hodge *et al.* teaches a method of generating a CD8+ T cell immune response in mice against a tumor antigen by administering a replicating vaccinia virus vector for priming and a non-replicating avian pox virus vector, either the ALVAC derived from canarypox or fowlpox virus, for boosting the expression of an epitope, the human carcinoembryonic antigen (CEA). See abstract and p. 760. The boosting composition is delivered intradermally by tail scarification. See p.762, Prime and boost studies.

Thus, claims 1, 2, 6, 7, 10, 12, and 14 are anticipated by Hodge *et al.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6, 7, 10, 12, and 14-16 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hodge *et al.* (1997) in view of Stoute *et al.* (1997).

The instant invention is further limited to a SBAS2 adjuvant.

The relevance of Hodge *et al.* is set forth above. Hodge *et al.* does not disclose the SBAS2 adjuvant.

Stoute *et al.* describes malaria vaccine formulations in three kinds of adjuvants: alum and monophosphoryl lipid A (SBAS4), an oil-in-water emulsion (SBAS3), and an oil-in-water emulsion plus the immune stimulants monophosphoryl lipid A and QS21 (SBAS2). See p. 87, Study Design and Vaccines. Stoute *et al.* further describes that SBAS2 is the most efficacious adjuvant. See p. 90, Discussion.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate the priming and boosting compositions of Hodge *et al.* in the SBAS2 adjuvant as taught by Stoute *et al.* One having ordinary skill in the art would have been motivated to do this because SBAS2 may also provide signals required to up-regulate co-stimulatory molecules on antigen-presenting cells, induce expression of molecules that permit these cells to travel to target tissues, or induce production of cytokines that mediate protection, as per suggested by Stoute *et al.* There would have been a reasonable expectation of success, given the results that the SBAS2 formulation proved superior for inducing strong antibody responses and strong antigen-specific delayed hypersensitivity in primates and proliferative and cytolytic T cell responses in mice, as taught by Stoute *et al.* Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-3, 6, 10, 12, 14, and 15 are rejected under 35 U.S.C. §103(a) as being unpatentable over Pialoux *et al.*(1995) in view of Egan *et al.* (1995, IDS No. AU9 on 28 October 2004).

The instant invention is a method for generating a CD8+ T cell immune response in a mammal against a target antigen, comprising administrating to a human a priming and booster vector, both are non-replicating or replication-impaired recombinant viral vector encoding one or more CD8+ T cell epitopes of the target antigen.

Pialoux *et al.* describes a prime-boost approach to generate CD8+ T cell response against HIV, by injecting health adults with recombinant canarypox vector expressing the HIV-1 gp160, from the MN isolate, in a formulation with an adjuvant. See abstract.

Pialoux *et al.* does not disclose non-replicating viral boosting vectors.

Egan *et al.* suggests administrating non-replicating canarypox vectors expressing HIV gp160 from the MN isolate. See abstract.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify vectors of Pialoux *et al.* to non-replicating viral vectors. One having ordinary skill in the art would have been motivated to do this to ensure the safety of the immunogenic vectors in humans, as per suggested by Egan *et al.*, who established a reasonable expectation of success by describing the administration of non-replicating ALVAC vector for the induction of CD8+ HIV-1-specific CTL in adult humans. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-3, 5, 6, 10, 12, 14, and 15 are rejected under 35 U.S.C. §103(a) as being unpatentable over Pialoux *et al.* (1995) in view of Egan *et al.* (1995), and further in view of Walker *et al.* (1989).

The instant invention is further limited to CD8+ T cell epitope comprising an amino acid sequence of SEQ ID NO:64.

The relevance of Pialoux *et al.* and Egan *et al.* is set forth above. Pialoux *et al.* and Egan *et al.* do not disclose SEQ ID NO:64.

Walker *et al.* explicitly suggests HIV-1 epitope in the reverse transcriptase of the amino acid sequence, NPDIVIYQYMDDLYVGSDLEIGQHR (peptide 50) to specifically stimulate CD8+ T cell immune response. See page 9517, left column, Table 4, line 12.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the epitope of Pialoux *et al.* and Egan *et al.* to the epitope comprising an amino acid sequence of SEQ ID NO:64. One having ordinary skill in the art would have been motivated to do this because the peptide 50 has been clearly defined as a potent CTL epitope from the most highly conserved region of HIV genome, as per suggested by Walker *et al.*, who established a reasonable expectation of success by describing that this epitope induces specific cytotoxicity in target cells. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Remarks

No claim is allowable.

Contact Informaiton

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Louise Humphrey, Ph.D.
Assistant Patent Examiner
20 June 2006

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